Business Stream Products
Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

AIR WATER REALIZE INC.
1320-5, Nagatoro, Kasama-shi,
Ibaraki-ken,
309-1712 Japan

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 20, 2024

Notified Body Confirmation Letter
Reference. : AIRWA_MDR Application 2024-04-15; order # 150294375

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

AIR WATER REALIZE INC.
1320-5, Nagatoro, Kasama-shi,
Ibaraki-ken,
309-1712 Japan
SRN Number: JP-MF-000029803

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD certificate expiry.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below.

- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function

On behalf of the Notified Body

Ning Chang

Ning N. C. Chang
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Disposable Needle	Class IIa	NA	HD 2014410-1 (NB#0197)
Dental Cartridge Needle	Class IIa	NA	HD 2014410-1 (NB#0197)
TERUMO DENTAL NEEDLE	Class IIa	NA	HD 2014410-1 (NB#0197)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/20	AIRWA_CL607_2024-05-20	Initial issue